is Target Lesion Failure (TLF) at 6-month for cohort 1 and at 12-month for cohort 2. For some patients also 18-month and 24-month imaging data are available.

RESULTS TLF rate at 36-month was 6.8% including 2 TLRs and 1 peri-procedural MI occurring at the 12-month follow-up angiography; no events emerged from 12- to 36-month. No cardiac death or scaffold thrombosis was observed.

Vasoconstriction after acetylcholine at 6-month (delta=-10.04%; p=0.0008 versus baseline) followed by vasodilatation after nitroglycerine(delta=8.69%; p<0.0001 versus baseline) demonstrates the uncaging aspect of the absorption process with no further change at the 12-month follow-up. Six-month virtual histology (VH) data showed a significant decrease in the dense calcium by 39.5% (p=0.0015) remaining stable from 6- to 12-month follow-up. This decrease is interpreted as a surrogate assessment for the bioabsorption process of the scaffold material.

Echogenicity data using the decrease in intensity of the ultrasound signal to quantify the change in strut structure demonstrate a continuous decrease in % hyperechogenicity over the follow-up period, with the most pronounced changes within the first 6 months (22 to 16% p<0.001).

CONCLUSION DREAMS shows excellent safety and efficacy data with no death and no scaffold thrombosis up to 3 years in the BIOSOLVE-I trial. Multi-modality imaging documented the absorption process and the uncaging aspect of this device already at 6 months.

CRT-716

Six-month Revascularization Outcome Of Jetstream Atherectomy In Treating In-stent Restenosis Of Femoropopliteal Arteries: Results Of The Jetstream-ISR Study

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BACKGROUND Treatment of in-stent restenosis (ISR) of the femoropopliteal (FP) artery is complex and is associated with high rate of restenosis. Debulking of FP ISR lesions have been attempted to reduce restenotic tissue burden and improve patency or target lesion revascularization (TLR). Recently laser atherectomy of FP ISR was shown to reduce target lesion revascularization at 6 months when compared to plain old balloon angioplasty (POBA) alone.

JetStream Atherectomy (JS) is a rotational cutter with aspiration capacity that has been shown to cut and remove atherosclerotic and restenotic tissue. Its application within a stented FP artery is off label. In this study, JS Navitus L or XC was applied prospectively in a cohort of FP ISR from 2 centers to evaluate acute procedural and 6-month outcomes and stent-device interaction. Data on 40 infrainguinal ISR lesions treated with the older generation Pathway PV atherectomy system were previously reported from Europe and no safety concerns were raised. The primary patency rate, however, was low at 33 % after 12 months. Since then, the device was upgraded to the JetStream Navitus with enhanced cutting ability and aspiration. This is the first prospective report on the off label use of the Jetstream Navitus XC atherectomy device in treating FP ISR (clinicaltrials.gov identifier NCT01722877).

METHODS 29 patients (32 limbs) with FP ISR were treated at 2 medical centers by 2 operators from October 2012 to August 2014. Patients were consented prior to the procedure and were included in the study only if they were found to have an in-stent restenotic lesion in the FP segment. The Jetstream device was used as a first modality of treatment. No other debulking devices, cutting/scoring balloons or cryogenic balloons were allowed. Adjunctive treatment was limited to POBA using a semi or non-compliant peripheral vascular balloon or stenting only if significant residual narrowing (>30%) remained or a significant dissection (type C or higher) was seen. It was recommended that the Jetstream be used to maximize debulking until the residual stenosis ≤ 50% prior to adjunctive therapy. The study was approved by the Institutional Review Board (IRB) at both institutions. Demographics, clinical, procedural and angiographic variables were prospectively collected. Quantitative vascular angiography was performed on lesions at baseline, post atherectomy alone and post adjunctive treatment. Six-month follow up was achieved on all patients (except 3 at the time of this writing). In-hospital and 6-month major adverse events were recorded. The primary effectiveness endpoint was acute procedural success defined as obtaining angiographically ≤ 30% residual narrowing with no serious adverse events at the end of the procedure. The primary safety endpoint was major adverse events in-hospital and at 6 months which included device-induced vascular injury as reported by the operator, amputation (major and minor unplanned), death, significant distal embolization requiring the use of pharmacologic or mechanical means to treat (other than a vasodilator), perforation, major bleeding, myocardial infarction as defined by ACC criteria, stroke, access complications (AV fistula and pseudoaneurysm), acute renal failure and acute (≤ 24 hours) or subacute (than 24 hours) vessel closure. Secondary endpoints included acute device success defined as a residual narrowing of ≤ 50% by the JetStream device alone and before adjunctive treatment and with no serious adverse events, distal embolization, clinically driven TLR and TVR at 6-month follow up based on symptom recurrence, ankle brachial indices (ABI), Rutherford- Becker class at one month and 6 month, death, and amputation. Device-stent untoward interaction was evaluated by an independent angiographic core laboratory. Descriptive analysis was done on all variables. Continuous variables were presented as mean ± SD and dichotomous variables as percentages. Kaplan-Meier survival curve for TLR was plotted.

RESULTS 29 consecutive patients (32 limbs) (mean age 72.5 ± 11.1 years, 34.5% males) were included in the study. One patient withdrew from the study. Six-month follow-up was completed on 25 patients. Adjunctive balloon angioplasty was performed in 100% at a mean pressure of 12.2 ± 3.2 atm. Lesion length was 16.6 ± 12 cm and total treated length 23.7 ± 18.8 cm. Acute procedural success occurred in 100% of patients. Acute device success was 75.8%. Embolic filter protection (EFP) was used in 16/32 (50.0%) of limbs. Macrodebris was noted in 2/16 (12.5%) of filters and distal embolization (DE) requiring treatment was 9.4% (2 with no EFP (one after adjunctive PTA), 1 with Spider EFP, 0 with Nav-6 EFP). There were no new stent fractures (n=24) post JS as reported by Core Lab analysis. On 6-month follow-up TLR occurred in 14.3% (Figure 1), patency rate (PSVR<2.4) 16/23 (70%), total death 4% (1/25), vascular related death 0%, major bleeding 0%.

CONCLUSION JS atherectomy using the Navitus device has favorable acute results in treating in-stent restenosis of the FP arteries with no device-stent interaction and high procedural success. At 6-month follow-up TLR compares favorably to historic controls from balloon angioplasty or other atherectomy devices. A multicenter randomized trial is needed to confirm these results.

CRT-718

Early In Vivo Evaluation of Strut Healing Following Bioresorbable Polymer Everolimus Eluting Stent Implantation in Humans: The TIMELESS Study

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Bioresorbable polymer DES technologies promise to enhance vascular healing by reducing the polymer exposure to the vessel wall potentially allowing the earlier discontinuation of dual anti-platelet therapy. At the present time, the in vivo early vascular healing response to this type of technologies is still unclear. The TIMELESS study is a multi-center, prospective, single arm study enrolling real world patients undergoing PCI. All patients underwent Synergy stent implantation (Boston Scientific Corp, MA, USA) using the Element Platinum-chromium platform coated with an ultra-thin abluminal bioabsorbable PLGA polymer eluting Everolimus. At 3 months, all patients underwent OCT imaging and Clopidogrel was stopped regardless of the OCT findings. A total of 37 patients were included in the study. The majority of the patients underwent PCI due to acute coronary syndromes (~65%). The mean vessel reference diameter was 2.63 ± 0.40 mm and 67.5% of the cases received stents longer than 20 mm in length. At 3 months, angiographic follow up showed a percentage diameter of stenosis of 8.1% ± 7.5% and an angiographic late loss of 0.03 ± 0.24 mm. A total of 7,761 struts (209.9 ± 45.8 struts per stent) were analyzed using OCT imaging. Full OCT analysis will be available at the time of the presentation.